

REMARKS

Applicants canceled claims 12 and 13 without prejudice or disclaimer. Applicants added new claims 14 to 35. Claims 14 to 35 are pending.

The specification also has been amended to include information that had initially been incorporated by reference. Specifically, U.S. Patent No. 4,760,130 (the '130 patent) was incorporated by reference on page 3, lines 1 and 2 of the initially-filed specification. The sequence information from the '130 patent is added to the first paragraph at page 5 of the present specification, where the '130 patent is cited. The '130 patent discloses the sequence with various R groups, e.g., at column 4. That disclosure indicates that R1 and R7 can be any substituted or unsubstituted amino acid residue, and provides particular amino acids for R2 to R6, R8, and R9, which are included in the material added in the amendment above. The paragraph following the added sequence is found in the '130 patent at column 8, lines 55 to 65.

The specification has also been amended to replace the original Sequence Listing with a Substitute Sequence Listing. The Substitute Sequence Listing was needed since new SEQ ID NO:4 was added to the claims and to the specification as discussed above. The Substitute Sequence Listing includes the addition of SEQ ID NO:4.

Applicants submit the attached Substitute Sequence Listing, to be inserted into the specification, along with a computer-readable form of that Substitute Listing. Please replace the original Sequence Listing, with this Substitute Sequence Listing.

The undersigned states that, to the best of his knowledge, the content of the Substitute Sequence Listing and the computer-readable copies of the Substitute

Sequence Listing submitted in accordance with 37 C.F.R. §§ 1.821(c) and (e), respectively, are the same. The specification, including the claims, includes the Substitute Sequence Listing identifier designations. The undersigned further states that, to the best of his knowledge, the Substitute Sequence Listing does not include new matter.

Claims 14 and 24 have been added and they include the sequence information added to the present specification as discussed above. Claims 14 and 24 include the specific possibilities of R1 and R7 being serine or alanine and include the possibility of R8 and/or R9 being leucine. The '130 patent discloses a sequence where R1 is serine, R7 is alanine, and R8 and R9 are leucine, e.g., at column 6, starting at line 40. Also, various embodiments in which R8 may or may not be leucine are described in the '130 patent, e.g., at columns 7 and 8.

Dependent claims 17 to 20, 23, 29 to 32, and 35 are directed to certain particular embodiments having particular R groups. Those substitutions are selected from the groups set forth in the amendment to the specification discussed above.

Support for new claims 22 and 34 can be found in the initially-filed specification, e.g., at page 7, lines 15 to 23.

Support for new claims 15, 16, 27, and 28 can be found in the initially-filed specification, e.g., at page 9, third paragraph, and at page 10, first full paragraph.

Support for new claims 21 and 33 can be found in the initially-filed specification, e.g., at page 12, first full paragraph.

Support for new claims 25 and 26 can be found in the initially-filed specification, e.g., at page 3.

The Examiner rejected claims 12 and 13 under the judicially-created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1 to 4, 10 to 18, and 23 to 25 of U.S. Patent No. 6,017,880 (the '880 patent). Action at page 3. Solely to expedite prosecution, a terminal disclaimer will be submitted if the currently pending claims are otherwise indicated as being allowable. It would be premature to submit a terminal disclaimer until such time.

The Examiner also rejected claims 12 and 13 under the judicially-created doctrine of obvious-type double patenting as allegedly being unpatentable over claim 12 of U.S. Patent No. 6,132,990 (the '990 patent). Action at page 3. The Examiner contended that "the conflicting claims . . . are not patentably distinct from each other because a method of the patented claim 12 for treating a serine protease-mediated condition comprising administration of a serine protease inhibitor [SLPI] protein comprising a SLPI domain of the patented claim 1 embraces methods for inhibition of viral, and specifically retroviral, proliferation of claims 12 and 13 . . . because retroviral proliferation is, according to the instant specification, mediated by a serine protease inhibited by SLPI." *Id.* at pages 3 to 4. Applicants respectfully traverse this rejection.

Applicants respectfully assert that the issue is whether issuance of present claims 14 to 35 would extend the rights conferred by claim 12 of the '990 patent, not whether claim 12 embraces methods according to claims 14 to 35. Claims 14 to 35 do not extend the rights conferred by claim 12 of the '990 patent, since claims 14 to 35 are directed to a subset of the methods encompassed by claim 12. After claim 12 of the '990 patent expires, anyone will be free to practice the method of claim 12 after such expiration, as long as they do not practice the subset methods of claims 14 to 35.

This very situation was addressed in *In re Kaplan*, 229 U.S.P.Q.2d 678 (Fed. Cir. 1986), and the Federal Circuit reversed the Examiner's double patenting rejection. The Court stated:

Any patent granted on the application at bar will have the single claim on appeal which is expressly limited to carrying out the Kaplan process [the prior patent's claimed process] using the specific solvent *mixture* of tetraglyme and sulfolane invented by appellants. Is this an extension of a patent on Kaplan's invention -- Kaplan who never conceived of using that mixture? When Kaplan's (sole) patent expires, and assuming appellants get their joint patent, the world will still be free to use (so far as those two patents go) the Kaplan process so long as appellants' solvent mixture is not used in it. Of course, it may be that everyone will want to use the improvement, but that is commonly the case when dominating patents expire with improvement patents still outstanding.

Id. at 681-682.

The Court continued by pointing out the distinction between domination and double patenting: "One of the simplest, clearest, soundest and most essential principles of patent law, is that a later invention may be validly patented, altho [sic] dominated by an earlier patent, whether to the same inventor or to a different inventor." *Id.* at 682, quoting E. Stringhams *Double Patenting* (1933) at 207, previously quoted in *In re Sarett*, 140 U.S.P.Q. 474 (C.C.P.A. 1964). The Court concluded that "[d]omination is an irrelevant fact." *Id.* at 682.

The Court held that a proper double patenting rejection requires a showing that the "later issuance of a second patent will continue protection, beyond the date of expiration of the first patent, **of the very same invention claimed therein** (same invention type double patenting) or of a mere variation of that invention which would have been obvious to those of ordinary skill in the relevant art (obviousness-type double patenting)." *Id.* at 683, emphasis added. Finding that the Examiner failed to establish

that the claimed method employing the specific mixture was the same as, or would have been obvious in view of, the patented method claim employing a generic organic solvent, the Court reversed the double patenting rejection. *Id.* at 683-684.

The Examiner here has not established that claims 12 and 13, and new claims 14 to 35, would have been obvious in view of claim 12 of the '990 patent. Since present claims 14 to 35 would not extend the protection (1) of the very same invention of claim 12 of the '990 patent or (2) of an obvious variant of claim 12, the provisional double patenting rejection should be withdrawn. Thus, applicants respectfully request reconsideration and withdrawal of the rejection over claim 12 of the '990 patent.

The Examiner rejected claims 12 and 13 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Action at page 4. Specifically, the Examiner contended that "[t]he claims fail to particularly point out and distinctly claim Applicant's intended subject matter because they do not indicate the positions for amino acid sequence alteration that could result in a generic SLPI in the context of any particular amino acid sequence." *Id.*

Solely to expedite prosecution and not acquiescing in the rejection, claims 12 and 13 have been canceled and new claims 14 to 35 have been added. New claims 14 to 35 include specifically recited sequences. Accordingly, the § 112, second paragraph, rejection is moot.


Applicants respectfully request that the Examiner indicate that the claims are allowable, but for the double patenting rejection over the '880 patent. Applicants will then file a terminal disclaimer of the '880 patent.

Please grant any extensions of time required to enter this response and charge
any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 15, 2004

By: 
M. Paul Barker
Reg. No. 32,013